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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,579	12/09/1999	MILES B. BRENNAN	3718-6	9014

757 7590 05/19/2003

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT PAPER NUMBER

1647

DATE MAILED: 05/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicant(s)

09/458,579

BRENNAN ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 15, 16, 19, 20, 22-29 and 35-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 15 and 16 is/are allowed.
- 6) ☒ Claim(s) 19, 20, 22-29 and 35-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/28/03 has been entered. An action on the RCE follows.

2. Claims 30-34 and 38 have been cancelled. Claims 1-5, 15, 16, 19, 20, 22-29 and 35-37 are pending. Claims 1-5, 15 and 16 are allowed.

3. The text of those sections of title 35, U. S. Code not included in this action can be found in the previous office actions.

#### ***Claim Rejections - 35 USC § 112, maintained***

4. Rejections of claims 19-20, 22-29 and 35-37 under USC 112, first paragraph, for lacking written description is maintained for reasons set forth in Paper No: 21 (9/25/02) and below. Applicant's arguments filed on 1/25/03 (Paper No: 23) have been fully considered but are not persuasive. Although, the Office agrees with the Applicant that MC1-R through MC5-R are described in the specification, there are no disclosures that any other melanocortin receptors other than MC2-R and MC5-R with a role in regulating body weight and energy homeostasis. Furthermore, the evidence provided by the Applicant on page: 7 of the response only indicates that the expression of the MC1-R and MC3-R receptors was previously known. However, it does not shed any insight into the role of these receptors in regulating body weight and energy homeostasis.

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Therefore, the Applicant at the time of filing did not contemplate or appreciate that MC1-R and MC3-R receptors were involved in the regulating body weight and energy homeostasis.

5. Rejections of claims 19-20, 22-29 and 35-37 under USC 112, first paragraph, for failing to satisfy the scope of enablement requirement is maintained for reasons set forth in Paper No: 21 (9/25/02) and above in paragraph 4. Applicant's arguments filed on 1/25/03 (Paper No: 23) have been fully considered but are not persuasive. Applicant submits that the melanocortin receptor genes and proteins were well known. This point is not in dispute. Although, the specification discloses melanocortin receptors MC1-R through MC5-R, it appears that the Applicant recognized only MC2-R and /or MC5-R to be the peripheral receptors with the ability to stimulate lipolysis and/or to inhibit fatty acid uptake by adipocytes, and in particular, to control obesity (see pages: 65-68; page: 76, lines 23-25). There is no correlation or suggestion of other melanocortin receptors namely MC1-R and MC3-R being involved in the regulation of body weight and energy homeostasis. Despite the knowledge in the art of the other melanocortin receptors, the specification fails to provide any guidance to the use of MC1-R and MC3-R in the regulation of body weight and energy homeostasis. Therefore the amount of experimentation required to make and/or use the full scope of claimed receptors would require undue trial and error experimentation. Given the breadth of claims 19-20 and 22-29 in light of the unpredictability of the art as determined by the lack of working examples and shown by the prior art of record, the level of skill of the artisan, and the lack of guidance provided in the instant specification, it would require undue

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experimentation for one of ordinary skill in the art to make and use the full scope of the claimed invention. Claim 20, 36 and 37 are rejected insofar as they depend on claims 19 and 35.

6. Claims 1-5, 15 and 16 are allowed. Claims 15-16, 19-20, 22-29 and 35-37 are rejected. However, claims that are drawn to methods of using MC2-R and MC5-R receptors for the detection of compounds involved in the regulation of bodyweight and energy homeostasis remain allowable over prior art.

#### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

js  
May 16, 2003



**LORRAINE SPECTOR  
PRIMARY EXAMINER**